We claim:

1. A device for injecting bone cement, comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions, and
ii) a sterile inner surface forming an entry opening in the first end portion and an exit opening in the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c) an impermeable first piston disposed within the inner surface of the injection chamber.

2. The device of claim 1 wherein the first and second end portions of the injection chamber define a first axis within the inner surface, wherein the first piston comprises a sidewall having a shape corresponding to the inner surface of the injection chamber, and the first piston is received within the inner surface to allow axial movement of the first piston along the first axis within the inner surface.

3.The device of claim 2 wherein the first piston is slidably received within the inner surface to allow sliding movement of the first piston along the first axis within the inner surface.

4. The device of claim 2 wherein the shape of the first piston sidewall provides substantial sealing engagement with the inner surface.

5. The device of claim 2 wherein the first piston has an inner face facing the exit opening of the injection chamber, the inner face has a centerpoint, and the centerpoint and exit opening of the injection chamber define a flowpath which is substantially linear.

6. The device of claim 5 wherein the flow path has an angle of less than 30 degrees.

7. The device of claim 2 further comprising an O-ring disposed between the sidewall of the first piston and the inner surface of the injection chamber.

8. The device of claim 2 wherein inner surface of the injection chamber has a tubular shape corresponding to the first axis, the sidewall has a threaded surface, and the tubular inner surface is correspondingly threaded for receiving the threaded sidewall to allow axial movement of the inner face of the first piston along the inner surface.

9. The device of claim 2 wherein the first piston has an inner face facing the exit opening of the injection chamber, and the inner face is movable within the inner surface from a first position in the first end portion of the injection chamber to a second position in the second end portion of the injection chamber,
wherein the first position of the first piston allows for fluid communication between the entry and exit openings of the sterile inner surface of the injection chamber, and
wherein the second position of the first piston restricts fluid communication between the entry and exit openings of the sterile inner surface of the injection chamber.

10. The device of claim 9 wherein the first and second positions define a maximum distance over which the first piston is movable along the first axis, and wherein the movement of the inner face from the first position to the second position defines an inner surface volume of between 0.1 cc and 5cc.

11. The device of claim 10 wherein the movement of the inner face from the first position to the second position defines an inner surface volume of between 0.5 cc and 2 cc.

12. The device of claim 9 wherein the entry opening has a diameter, and the first piston sidewall has a length greater than the diameter of the entry opening.

13. The device of claim 9 wherein the exit openings are in fluid communication when the inner face of the first piston is located in the first end portion.

14. The device of claim 9 wherein the sidewall of the first piston and the inner surface are in sealing connection, and the inner face of the first piston is movable from the second position to the first position.

15. The device of claim 9 wherein the second position of the first piston inner face is substantially adjacent to the exit opening.

16. The device of claim 2 further comprising:

d) means for axially moving the first piston with mechanical advantage.

17. The device of claim 1, further comprising:

d) a shaft having a first end portion and a second end portion,

wherein the first piston further comprises an outer face, the second end portion of the inner surface has a third opening, the outer face of the piston is connected to the first end portion of the shaft, and the second end portion of the shaft is slidably received in the third opening.

18. The device of claim 17 further comprising:

e) a lever having first and second ends, the first end of the lever being connected to the device, the second end of the lever positioned to bear upon the second end of the shaft, wherein at least one end portion of the lever is pivotally connected.

19.The device of claim 17 further comprising:

e) a lever having first and second ends, the first end of the lever being pivotally connected to the device, the second end of the lever positioned to bear upon the second end of the shaft.

20. The device of claim 19 wherein the second end of the lever contacts the second end of the shaft.

21. The device of claim 19 wherein the second end of the lever is connected to the second end of the shaft.

22. The device of claim 19 wherein the second end of the lever is attached to the second end of the shaft.

23. The device of claim 19 wherein the second end of the lever is pivotally attached to the second end of the shaft.

24. The device of claim 19 further comprising:

f) an arm having a first end attached to the device and a second end attached to the first end of the lever, wherein at least one end of the arm is pivotally attached.

25. The device of claim 17 further comprising:

d) a lever having first and second ends, the first end of the lever positioned to bear upon the device, the second end of the lever being pivotally connected to the second end of the shaft.

26. The device of claim 25 wherein the first end of the lever contacts the device.

27. The device of claim 25 wherein the first end of the lever is connected to the device.

28. The device of claim 25 wherein the first end of the lever is attached to the device.

29. The device of claim 25 wherein the first end of the lever is pivotally attached to the device.

30. The device of claim 18 wherein the second end of the lever bears against the second end of the shaft at a location to produce a mechanical advantage of more than 1.

31. The device of claim 17 wherein the outer face of the piston is integral with the first end portion of the shaft.

32. The device of claim 1 further comprising a check valve located downstream of the reservoir, the check valve being biased in a normally closed position sealing the exit opening, the check valve being automatically openable in response to increased pressure within the injection chamber and automatically recloseable upon reduction of the pressure increase below a predetermined level.

33. The device of claim 1 further comprising a check valve located downstream of the reservoir for sealing the exit opening, the check valve being manually openable and closeable.

34. The device of claim 1 wherein the first piston has an inner face, and further comprising d) a flow restrictor disposed within the inner surface of the injection chamber between the inner face of the first piston and the exit opening of the injection chamber, the restrictor comprising a slitted sheet normally disposed parallel to the inner face of the first piston, wherein the slitted sheet comprises flaps formed by slits, wherein said flaps are oriented towards the exit opening of the injection chamber in response to increased pressure from the direction of the first piston, and the flaps return to a position parallel to the inner face upon reduction of the increased pressure, thereby restricting backflow.

35. The device of claim 1 further comprising means for restricting back flow, the means disposed within the inner surface of the injection chamber between the inner face of the first piston and the exit opening of the injection chamber.

36. The device of claim 1 further comprising:

d) a second piston disposed within the reservoir and having an inner face facing the exit opening of the reservoir,

wherein the first piston has an inner face facing the exit opening of the injection chamber, and wherein the inner faces of the first and second pistons define respective first and second cross-sectional areas, and wherein the ratio of the second cross-sectional area to the first cross-sectional area is at least 9:1.

37. The device of claim 1 further comprising:

d) a valve positioned between the first opening of the sterile inner surface of the injection chamber and the exit opening of the reservoir for restricting the fluid communication therebetween.

38. A device for injecting bone cement, comprising:

a) a reservoir having an exit opening and an inner surface,

b) an injection chamber having:

i) first and second end portions, and

ii) a sterile inner surface forming an entry opening in the first end portion and an exit opening in the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

wherein the reservoir inner surface and the injection chamber inner surface define a volume ratio of at least 10:1.

39. The device of claim 38 wherein the reservoir inner surface and the injection chamber inner surface define a volume ratio of at least 20:1.

40. A device for injecting bone cement, comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions, and
ii) a sterile inner surface forming an entry opening in the first end portion and an exit opening in the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

wherein the injection chamber inner surface defines a volume of between 0.1 and 5 cc.

41. The device of claim 40 wherein the injection chamber inner surface defines a volume of between 0.5 and 2 cc.

42. The device of claim 40 further comprising:

c) a shaft having a mixing shank extending therefrom,

wherein the reservoir further comprises an inner surface and first and second ends defining a reservoir axis within the inner surface of the reservoir,

and wherein the shaft is axially disposed within the reservoir.

43. The device of claim 43 wherein the shank is a disc having transverse holes therethrough, the shaft has first and second ends, the disc is attached to the first end of the shaft, the second end of the reservoir has a fourth opening, and the second end of the shaft is slidably received in the fourth opening.

44. The device of claim 40 further comprising:

c) a second piston housed within the reservoir and having an inner face facing the exit opening of the reservoir.

45. The device of claim 44 wherein the second piston has a sidewall corresponding to the inner surface of the reservoir, and the second piston is slidably received in the inner surface of the reservoir.

46. The device of claim 45 wherein the shaft has a first end facing the exit opening of the reservoir, the second piston has an outer face, and wherein the first end of the shaft bears against the outer face of the piston.

47. The device of claim 46 further comprising:

d) means for locking the second piston to a predetermined location along the reservoir axis.

48. The device of claim 46 wherein the reservoir has an exterior surface, and the fourth opening defines a mating surface on the exterior surface, and wherein the shaft has a mating shank having a corresponding shape for bearing against the mating surface.

49. The device of claim 44 wherein the inner face of the second piston is in substantial sealing connection with the inner surface of the reservoir.

50. The device of claim 44 further comprising a compression spring having a first end, wherein the second piston has an outer face, and the first end of the spring bears against the outer face of the second piston.

51. The device of claim 50 wherein the reservoir comprises first and second end portions, the exit opening of the reservoir is disposed in the first end portion of the reservoir, and a fourth opening is disposed in the second end portion of the reservoir, the device further comprising:

d) a shaft axially disposed within the reservoir and slidably received in the backside opening.

52. The device of claim 51 wherein the compression spring defines an inner tube, and the shaft is axially disposed within the inner tube of the compression spring.

53. The device of claim 52 wherein the shaft has a first end facing the exit opening of the reservoir, the second piston has an outer face, and wherein the first end of the shaft bears against the outer face of the piston.

54. The device of claim 44 further comprising:

d)a locking pin comprising a tyne,

wherein the reservoir has a transverse hole for receiving the tyne, the second piston has a sidewall having a recess shaped for receiving the tyne, and the tyne is inserted through the reservoir hole and is received within the recess of the second piston.

55. A device comprising:

a) a reservoir having an axis and an exit opening,

b) an injection chamber having:

i) first and second end portions and

ii) a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c) a radially movable mixing element housed within the reservoir.

56. The device of claim 55 wherein the mixing element is axially movable.

57. The device of claim 56 wherein the mixing element is unconstrained within the reservoir.

58. The device of claim 55 wherein the mixing element comprises a sphere.

59. A device comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions, and

ii)a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c) means for preventing back flow from the exit opening of the injection chamber.

60. The device of claim 59 wherein the means comprises a check valve located near the exit opening in the injection chamber, the check valve biased in a normally closed position sealing the exit opening of the injection chamber from fluid communication with the entry opening, the valve being openable in response to increased pressure within the injection chamber and recloseable upon reduction of the pressure increase below a predetermined level.

61. The device of claim 60 wherein the check valve is located in the exit opening of the injection chamber.

62. The device of claim 60 further comprising:

d)a first piston disposed in the inner surface of the injection chamber and having an inner face, and

e)a flow restrictor disposed within the inner surface of the injection chamber between the inner face of the first piston and the exit opening of the injection chamber, the restrictor comprising a slitted sheet normally disposed parallel to the inner face of the first piston, wherein the slitted sheet comprises flaps formed by slits, wherein said flaps are oriented towards the exit opening of the injection chamber in response to increased pressure from the direction of the first piston, and the flaps return to a position parallel to the inner face upon reduction of the increased pressure, thereby restricting backflow.

63. A device for injecting bone cement, comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions and

ii) a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c) means for manually ejecting bone cement in discrete quantities from the injection chamber under a pressure of at least 1000 psi.

64. The device of claim 63 wherein the means comprises means for occluding the fluid communication between the entry and exit openings of the injection chamber.

65. The device of claim 64 wherein the integral means comprises means for moving the bone cement through the injection chamber.

66.The device of claim 65 wherein the integral means comprises an impermeable first piston disposed within the inner surface of the injection chamber, the first piston being movable over the entry opening of the sterile inner surface of the injection chamber.

67. The device of claim 66 wherein the first piston comprises an inner face facing the exit opening and a cylindrical surface extending from the inner face and facing the inner surface of the injection chamber.

68. The device of claim 63 wherein the inner surface of the injection chamber is between 0.1 cc and 5 cc.

69. A device for injecting bone cement comprising:

a) a reservoir having first end portion forming an exit opening and a second end portion,

b) an injection chamber having:

i) first and second end portions and

ii) a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c) means for applying continuous pressure upon bone cement located in the reservoir.

70. The device of claim 69 wherein the means comprises a compression spring having:

i) a first end facing the exit opening of the reservoir, and

ii)a second end extending away from the exit opening of the reservoir and contacting the second end portion of the reservoir defining a location.

71. The device of claim 70 further comprising:

d) a second piston disposed within the reservoir and having an inner face facing the exit opening of the reservoir.

72.The device of claim 71 wherein the inner face of the second piston is located between exit opening of the reservoir and the first end of the spring.

73.The device of claim 72 wherein the second piston has an outer face contacting the first end of the spring.

74.The device of claim 73 wherein the spring has a relaxed length, and wherein the relaxed length is no less than the distance between the exit opening of the reservoir and

the location where the second end of the spring contacts the second end portion of the reservoir, thereby enabling the second piston to approach the exit opening.

75.The device of claim 74 further comprising a first piston disposed within the injection chamber, the first piston having an inner face which is movable from a location near the exit opening to a location in the first end portion of the injection chamber.

76. An injection device for injecting bone cement, comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions, and

ii) a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c)mechanical advantage means for pressurizing the injection chamber.

77. An injection device for injecting bone cement, comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions, and

ii) a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween,

c) a shaft having a first end portion and a second end portion,

wherein the second end portion of the inner surface has a third opening and the second end portion of the shaft is slidably received in the third opening, and

d) a lever having first and second end portoins, the first end of the lever being connected to the device, the second end of the lever positioned to bear upon the second end portion of the shaft, wherein at least one end portion of the lever is pivotally connected.

78. The device of claim 77 wherein the first end portion of the lever is pivotally attached to the device.

79. An injection device for injecting bone cement, comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions, and

ii) a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c) means for creating a vacuum in the injection chamber between the entry and exit openings.

80. The device of claim 79 further comprising:

d) means for maintaining pressure within the reservoir.

81. The device of claim 80 wherein the means for creating a vacuum comprises a first piston disposed within the inner surface of the injection chamber.

82. A device comprising:

a) a reservoir having an exit opening,

b) an injection chamber having:

i) first and second end portions and
ii) a sterile inner surface forming an entry opening disposed at the first end portion and an exit opening disposed at the second end portion,

the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween, and

c) an O-ring contacting the inner surface of the injection chamber.

83. The device of claim 82 further comprising:

d) a first piston having a sidewall disposed within the inner surfaces of the injection chamber,

wherein the O-ring is disposed between the sidewall and the inner surface of the injection chamber.

84. An injection device for injecting bone cement, comprising:

a) a reservoir having an exit opening,

b) an injection chamber having i) a sterile inner surface forming entry and exit openings, and ii) first and second ends defining a first axis, the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween,

c) a first piston disposed within the inner surface of the injection chamber and having a first piston having an inner face facing the exit opening of the injection chamber,

d) a second piston disposed within the reservoir and having an inner face facing the exit opening of the reservoir, and

wherein the inner faces of the first and second piston define respective first and second cross-sectional areas, and wherein the ratio of the second cross-sectional area to the first cross-sectional area is at least 9:1.

85. A process comprising the steps of:

a) providing a powder mixture suitable for producing a bone cement, the powder mixture comprising between 20 wt% and about 40 wt% contrast agent,

b) mixing the powder mixture with a liquid component to form a viscous bone cement, and

d) injecting the viscous bone cement into a vertebral body.

86. A method of using a bone cement, comprising the steps of :

a) providing a bone cement having a setting time of at least 18 minutes, and

b) injecting the bone cement into a vertebral body.

87. A powder mixture for producing a bone cement comprising contrast agent grains having a D_{50} grain size of at least 2 um.

88. The powder mixture of claim 87 wherein the contrast agent grains are $BaSO_4$.

89. A powder mixture suitable for producing bone cement, the powder mixture comprising between 20 wt% and 40 wt% contrast agent and free initiator powder.

90. A powder mixture suitable for producing a bone cement, the powder mixture comprising between 16 wt% and 40 wt% free zirconia powder, and at least 40 wt% PMMA powder.

91. A powder mixture suitable for producing bone cement, the powder mixture comprising between 20 wt% and 40 wt% barium sulfate powder, wherein the barium sulfate powder grains are unagglomerated.

92. A formulation suitable for producing bone cement, comprising a powder component having:

a) between 20 and 40 wt% contrast agent and
b) no more than 1.1 wt% initiator powder.

93. A formulation suitable for producing bone cement comprising:

a) a liquid component comprising no more than 2.4 vol% accelerator, and
b) a powder component comprising between 20 wt% and 40 wt% contrast agent.

94. A powder mixture suitable for use as a bone cement, the powder mixture comprising:

a) between 20 wt% and 40 wt% contrast agent (preferably, barium sulfate),
b) no more than 50 wt% co-polymer.

95. A bone cement formulation comprising:

a) a powder component comprising between 20 wt% and 40 wt% contrast agent and an initiator present in an amount defining a powder initiator fraction, and
b) a liquid component comprising an accelerator present in an amount defining a liquid accelerator fraction,

wherein the ratio of the liquid accelerator fraction to the powder initiator fraction is less than 1.75.

96. A bone cement formulation comprising:

a) a powder component comprising between 20 wt% and 40 wt% contrast agent and an initiator present in an amount defining a powder initiator fraction, and
b) a liquid component comprising an accelerator present in an amount defining a liquid accelerator fraction,

wherein the ratio of the liquid accelerator fraction to the powder initiator fraction is between 1.3 and 1.9, and wherein the powder initiator fraction is less than 1.3%.

97. A bone cement formulation comprising:

a) a powder component comprising between 20 wt% and 40 wt% contrast agent and an initiator present in an amount defining a powder initiator fraction, and
b) a liquid component comprising an accelerator present in an amount defining a liquid accelerator fraction,

wherein the ratio of the liquid accelerator fraction to the powder initiator fraction is between 1.67 and 1.99, and wherein the liquid accelerator fraction is less than 2.6 vol%.

98. A bone cement formulation comprising:

a) a powder component comprising between 20 wt% and 40 wt% contrast agent and an initiator present in an amount defining a powder initiator fraction, and
b) a liquid component comprising an accelerator present in an amount defining a liquid accelerator fraction,

wherein the ratio of the liquid accelerator fraction to the powder initiator fraction is between 1 and 2, and wherein the liquid accelerator fraction is less than 1.9 vol%.

99. A process comprising the steps of :

a) providing a powder mixture suitable for producing a bone cement,

b) mixing the powder mixture with a liquid component to form a viscous bone cement, and

c) injecting the viscous bone cement into a vertebral body,

wherein at least a portion of the injection step occurs at least 10 minutes after the mixing step.

100. A method of injecting a bone cement into an interior region of a vertebral body, comprising the steps of:

a) providing a vertebroplasty injection device having an injection chamber and a reservoir in fluid connection therewith, the injection chamber and the reservoir each containing the bone cement,

b) fluidly connecting the injection chamber to the interior region of the vertebral body,

c)discretely injecting a first amount of bone cement from the injection chamber into the interior region of the vertebral body,

d)flowing bone cement from the reservoir to the injection chamber, and

e) discretely injecting a second amount of bone cement from the injection chamber into the interior region of the vertebral body.